

Memorandum

To: Joy Mele, MS

From: Mary Parks, MD

Subject: LABELING REVISIONS FOR MEVACOR (AFCAPS/TexCAPS).

Date: January 19, 1999

- *Page 2 Clinical Pharmacology section, 1st paragraph, 2nd sentence revised. Delete second paragraph describing AFCAPS/TexCAPS.*

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- *Page 8 Clinical Studies section, 1st and 2nd paragraph revised.*

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- *Page 9, Clinical Studies section, 1st sentence deleted and rest of paragraph revised.*

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- *Page 10, Clinical Studies section, Figure 1 to use survival curve to describe primary endpoint results.*
- *Page 12, Indications and Usage section, 1st paragraph, 1st sentence revised. Subheading for Primary Prevention of Coronary Heart Disease revised.*

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- *Page 28, Dosage and Administration section, 2nd paragraph, 3rd sentence revised.*

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- *Please note: Revisions for Warnings Section regarding liver function tests monitoring pending.*

cc: David Orloff, MD
Margaret Simoneau, RPh
Jayne Peterson, JD